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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,244	09/29/2003	Nasir Shahrestani	END-5034	1898
27777 7590 06/25/2008 PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003				
EXAMINER PANI, JOHN				
ART UNIT 3736		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/674,244

Applicant(s)

SHAHRESTANI ET AL.

Examiner

JOHN PANI

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2007.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-10 and 12-15 is/are pending in the application.
4a) Of the above claim(s) 12-15 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-4 and 6-10 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/9/2007 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In reference to Claims 1-4

In line 10 of claim 1 it is unclear whether "a request" is an additional request or is referring back to "an audio request" of line 2. The lack of clarity regarding the scope of the claim renders the claim and those claims which depend from it indefinite.

In reference to Claims 2 and 8

Line 1 states "the audio stimulus are at varying intensity levels". It is unclear whether the claim is requiring a single stimulus or multiple stimuli. The lack of clarity regarding the scope of the claim renders the claim indefinite.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4 and 6-10 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2005/0066971 to Donofrio ("Donofrio").

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In reference to Claims 1-4 and 6-10

Donofrio clearly anticipates claims 1-4 and 6-10 (see [0167-0173]).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-4 and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,745,764 to Hickie ("Hickie") in view of US 2003/0078515 to Menzel et al. ("Menzel") and the disclosure of the instant US Application 10/674,244 as admitted prior art.

In reference to Claims 1 and 6

Hickie teaches a conscious sedation system comprising: a controller/sub-controller (**256** and **14**) which generates an audio request for a predetermined response from a patient (col. 21 lines 20-25); a response testing apparatus including: a request assembly (**264**) which communicates to the patient the audio request generated by the controller (col. 21 lines 25-30); and a response assembly (**266**) which is used by the patient to generate the response and which communicates the response to the controller (col. 21 lines 33-41), wherein the controller is programmed to generate a request and to analyze the patient's response to the request (col. 21 lines 45-65). Hickie further teaches that the system is baselined (col. 29 lines 35-40), but does not explicitly describe how. Hickie does not teach that the controller is programmed to determine and record a baseline audio stimulus for the patient nor that after determining

the baseline audio stimulus, the controller generates a request based upon the baseline stimulus for monitoring the patient's level of sedation.

The instant US Application 10/674,244 teaches (see [00161]) that in the prior art, the baseline is established manually by increasing the intensity of the audio stimulus until the patient hears the stimulus and generates a request. The level of intensity at which the patient discerns the audio request is set as the baseline, and the baseline is used in the conscious sedation system as the initial stimulus level to assess the level of sedation of the patient. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a calibration procedure such as that taught in the admitted prior art in the system of Hickie because Hickie notes that the system is baselined but does not explicitly describe how, while the admitted prior art notes that the described method of baselining is known in the prior art, and it is obvious to use an art recognized method of accomplishing a desired goal in order to achieve that goal.

Menzel teaches a system for calibrating hearing tests in which a controller produces a stimulus (see [0157]). The controller asks the user if the stimulus can be heard. If the user responds that the stimulus was heard the controller automatically sets parameters of the device (see [0165]).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the system of Hickie in view of Menzel and the admitted prior art by modifying the controller so that it produced an audio signal, determined if the user heard it, and set an operating parameter based on it as taught by Menzel (particularly the baseline value for monitoring the patient's level of sedation, as

motivated by the admitted prior art), because it would automate a known process, thereby freeing the physician to focus on other tasks, etc. See MPEP § 2144.04 III.

In reference to Claim 7

Hickle in view of Menzel and the admitted prior art teach the method of claim 6 (see above) and Hickle further teaches that the request assembly generates an audio vibration stimulus to the patient (see col. 21 lines 25-30).

In reference to Claims 2 and 8

Hickle in view of Menzel and the admitted prior art teach the method of claims 1 and 6 (see above) and Hickle further teaches that the audio vibration stimulus is at varying intensity levels (col. 21 lines 35-45).

In reference to Claims 3, 4, 9, and 10

Hickle in view of Menzel and the admitted prior art teach the method of claims 1 and 6 (see above) and Hickle further teaches that the audio vibration stimulus is continuous (while being used) and discrete (in that it has a beginning and end).

Response to Arguments

8. Applicant's arguments filed 1/2/2007 have been fully considered but they are not persuasive. The Applicant's assertion (on pg. 7, final paragraph) that Menzel discloses features which the Applicant does not claim is not persuasive because the use of the transitional term "comprising" does not exclude additional features. See MPEP § 2111.03 [R-3].

9. Applicant's arguments (on pg. 7 final paragraph and pg. 8 lines 1-5) regarding Menzel's alleged deficiency in teaching "calibrating a system to a baseline audio stimulus representing a level of patient consciousness" and "a request assembly which communicates an audio request to the patient...to record a baseline audio stimulus" with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN PANI whose telephone number is (571)270-1996. The examiner can normally be reached on Monday-Friday 7:30 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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JP 6/18/08

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736